U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE ATTORNEY'S DOCKET NUMBER FORM FTO-1390 (REV 10-95) **MERCK 2330** TRANSMITTAL LETTER TO THE UNITED STATES U.S. APPLICATION NO. (If known, see 37 CFR §1 5) **DESIGNATED/ELECTED OFFICE (DO/EO/US)** CONCERNING A FILING UNDER 35 U.S.C. §371 INTERNATIONAL APPLICATION NO INTERNATIONAL FILING DATE PCT/EP00/05183 6 JUNE 2000 16 JUNE 1999 TITLE OF INVENTION SPRAY-DRYING INSTALLATION AND A METHOD FOR USING THE SAME APPLICANT(S) FOR DO/EO/US SCHWARZ, Eugen, et al. Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a filing under 35 U S.C. §371. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. §371. This express request to begin national examination procedures (35 U.S.C. §371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. §371(b) and PCT Articles 22 and 39(1). A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. A copy of the International Application as filed (35 U.S.C. §371(c)(2)) 5. is transmitted herewith (required only if not transmitted by the International Bureau). has been transmitted by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). A translation of the International Application into English (35 U.S.C. §371(c)(2)). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. §371(c)(3)) are transmitted herewith (required only if not transmitted by the International Bureau). have been transmitted by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. §371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. §371(c)(4)). A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. §371(c)(5)). Items 11. to 16. below concern document(s) or information included: 11. An Information Disclosure Statement under 37 C.F.R. §§1.97 and 1.98. 12. 🗆 An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. §§3.28 and 3.31 is included. A FIRST preliminary amendment. A SECOND or SUBSEQUENT preliminary amendment. 14. A substitute specification. 15. A change of power of attorney and/or address letter. 16. Other items or information:

A CAPPUT COLOR INTERNATIONAL APPLICATION NO U.S. APPLICATION NO (if known, see 37 CFR §1 5) ATTORNEY'S DOCKET NUMBER PCT/EP00/05183 MERCK 2330 CALCULATIONS PTO USE ONLY 17. The following fees are submitted: BASIC NATIONAL FEE (37 CFR §1.492 (a) (1) - (5)): Search Report has been prepared by the EPO or JPO..... \$890.00 International preliminary examination fee paid to USPTO (37 CFR §1.482)...... \$710 00 No international preliminary examination fee paid to USPTO (37 CFR §1.482) but international search fee paid to USPTO (37 CFR §1.445(a)(2))..... \$740.00 Neither international preliminary examination fee (37 CFR §1.482) nor international search fee (37 CFR §1.445(a)(2)) paid to USPTO..... \$1040.00 International preliminary examination fee paid to USPTO (37 CFR §1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)..... \$100.00 \$890.00 ENTER APPROPRIATE BASIC FEE AMOUNT = \square_{20} Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 C.F.R. §1.492(e)). **NUMBER EXTRA CLAIMS** NUMBER FILED RATE Total claims \$0.00 18 0 \$ 18.00 20 Independent claims 0 \$ 84.00 \$0.00 3 3 \$ 280.00 MULTIPLE DEPENDENT CLAIM(S) (1f applicable) TOTAL OF ABOVE CALCULATIONS = \$890.00 Reduction of 1/2 for filing by small entity, if applicable. A Verified Small Entity Statement must also be \$890.00 SUBTOTAL = \square 30 Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 C.F.R. §1.492(f)). \$890.00 TOTAL NATIONAL FEE = Fee for recording the enclosed assignment (37 C.F.R. §1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. §§3.28, 3.31). \$40.00 per property. TOTAL FEES ENCLOSED = \$890.00 Amount to be refunded: charged: to cover the above fees is enclosed. A check in the amount of \$890.00 in the Please charge my Deposit Account No. 13-3402 to cover the above fees. amount of A duplicate copy of this sheet is enclosed. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to 13-3402. A duplicate copy of this sheet is enclosed. Deposit Account No. NOTE: Where an appropriate time limit under 37 C.F.R. §§1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. §1.137(a) or (b)) must be filed and granted to restore the application to pending status. SEND ALL CORRESPONDENCE TO Customer Number 23,599 SIGNATURÈ

Anthony J. Zelano PATENT TRADEMARK OFFICE NAME Filed: 13 DECEMBER 2001 27,969 REGISTRATION NUMBER AJZ:kmo

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE

International Application No.

PCT/EP00/05183

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6 JUNE 2000

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16 JUNE 1999

Applicant(s) (DO/EO/US)

SCHWARZ, Eugen, et al.

Title: SPRAY-DRYING INSTALLATION AND A METHOD FOR USING THE SAME

PRELIMINARY AMENDMENT

Commissioner for Patents Washington, D.C. 20231

SIR:

Prior to calculating the national fee, and prior to examination in the National Phase of the above-identified International application, please amend as follows:

IN THE CLAIMS:

- 5. (Amended) The process as claimed in claim 1, characterized in that the gas is circulated.
- 6. (Amended) The process as claimed in claim 1, characterized in that the circulated gas is freed from particles by filters and re-fed to the spray nozzles or heated and introduced into the fluidized bed.
- 7. (Amended) The process as claimed in claim 1, characterized in that the gas is freed from particles with the aid of dynamic filters.
- 8. (Amended) The process as claimed in claim 1, characterized in that the liquid media used have different compositions at different points of the plant.

9. (Amended) The process as claimed in claim 1, characterized in that that particle sizes of from 50 to 1000 μ m can be established specifically by varying the parameters spray pressure, amount of liquid, amount of powder returned, hot-air stream and temperature of the hot air.

REMARKS

The purpose of this Preliminary Amendment is to eliminate multiple dependent claims in order to avoid the additional fee. Applicants reserve the right to reintroduce claims to canceled combined subject matter.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "Version With Markings to Show Changes Made".

Respectfully submitted,

Anthony J) Zelano, Reg. No. 27,969

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 5 - 9 have been amended as follows:

- 5. (Amended) The process as claimed in claims 1-and 4, characterized in that the gas is circulated.
- 6. (Amended) The process as claimed in claims 1, 4 and 5, characterized in that the circulated gas is freed from particles by filters and re-fed to the spray nozzles or heated and introduced into the fluidized bed.
- 7. (Amended) The process as claimed in claims 1 and 4 to 6, characterized in that the gas is freed from particles with the aid of dynamic filters.
- 8. (Amended) The process as claimed in claims 1 and 2, characterized in that the liquid media used have different compositions at different points of the plant.
- 9. (Amended) The process as claimed in claims 1 to 8, characterized in that that particle sizes of from 50 to 1000 µm can be established specifically by varying the parameters spray pressure, amount of liquid, amount of powder returned, hot-air stream and temperature of the hot air.

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PCT/EP00/05183

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Spray-drying plant, and process for the use thereof

The invention relates to a fluidized-bed apparatus with integrated spray drying and to a process for the use thereof. The invention also relates to a process for the production of spray-dried powder material whose product properties can be varied in a targeted manner depending on the further use.

15 Commercially available granular materials are usually produced by spraying a solution or suspension of one or more components into a spray tower charged with hot gas. In the stream of hot gas, the liquid components evaporate, and solid particles which have a more or less random shape form.

Also known is granulation in a fluidized bed, in which the stream of process air flows through a specially shaped feed base, generating a fluidized bed of solid starting material. The spray liquid enters fluidizing space in finely divided form through a nozzle system. The fluidizing particles are wetted, the surface is partially dissolved, and the particles adhere together. At the end of the fluidized bed, solid is removed continuously. At the same time, a smaller amount of solid finely divided in the spray liquid is fed in at the inlet. A filter system prevents dust leaving the fluidized bed and ensures granular material particles having a minimum size are removed at the outlet. Solid particles with a more less random shape likewise form in a fluidized bed of this type.

It is therefore an object of the invention to provide a suitable plant and a process for operating the plant with the aid of which properties of spray-dried or granulated, pulverulent products can be varied as

5 desired with respect to particle size, particle size distribution, moisture content and tabletting ability.

The object is achieved by a spray-drying plant which has

- 10 a) a spray-drying unit (B)
 - b) a fluidized bed (A)
 - c) one or more additional spray or atomization nozzles for liquid media (C)
 - e) a powder metering device (D)
- 15 f) a powder return (9) with fan (E).

In the spray-drying unit of the spray-drying plant according to the invention, (B) liquid medium (5), spray air (6), pulverulent material (9) and hot air (4) are combined.

20 are combined.

A particular embodiment consists in that a spray-drying unit (B) is located vertically above a downstream fluidized bed in a spray tower.

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In a specific embodiment, the spray-drying unit (B) of the plant can comprise a spray system which consists of a two-component spray nozzle heated by hot water with coaxially arranged powder return and hot-gas surrounding flow.

The object is achieved, in particular, by a plant in which one or more additional spray or atomization nozzles for liquid media (C) can be installed in the fluidized bed at variable locations. In accordance with the present invention, the fluidized bed is followed by a powder metering device (D), which is separated off by a paddle valve (F) and is fed by an overflow (8).

Some of the product formed can, in accordance with the invention, be returned, if desired after comminution, into the spray-drying unit (B) via a fly conveyor, in which a fan (E) serves as conveying element. The fan

5 (E) acting as conveying element can simultaneously serve as comminution unit for the returned powder.

The object is also achieved by a process for the production of spray-dried powder material in which

- 10 a) in a first step, a liquid medium, spray gas, pulverulent material and hot air are combined,
 - b) the pulverulent product formed falls into a fluidized bed, is taken up, fluidized and transported further,
- 15 c) in one or more granulation step(s), is sprayed with further liquid medium, dried and conveyed in the fluidized bed toward the powder metering device, from which
- d) some of the pulverulent material is returned into the process.

The liquid medium is a solution, a dispersion or a suspension.

25 A particular variant of the process consists in that the returned pulverulent material is comminuted before return.

The spray gas, carrier gas and heating gas used can be air or an inert gas selected from the group consisting of $N_{2...}$ and CO_{2} . The gas can, in accordance with the invention, be circulated, in which case it is freed from particles by means of filters or with the aid of dynamic filters and fed back to the spray nozzles or heated and introduced into the fluidized bed.

In accordance with the invention, liquid media used at various points of the plant can have different compositions.

The present object is also achieved, in particular, by allowing particle sizes of from 50 to 1000 μm to become established specifically by varying the parameters

5 spray pressure, amount of liquid, amount of powder returned, hot-air stream and temperature of the hot air.

In order to carry out the process, the plant is charged at the beginning with pulverulent starting material via 10 the fill port (3). A stream of air is generated in the spray-drying space via the chambers (1). The starting material introduced is fluidized by this stream of air and moves toward the discharge flap (F). The stream of 15 powder is given this movement direction on generation of the stream of air by an appropriate perforation of Conidur base. The fluidized product discharged by simply opening the paddle valve (F). At this point of the plant, devices are provided which enable the product to be fed either into a powder 20 metering device or via a fly conveyor to the spraydrying unit. An overflow (8) for the finished product is located at the outlet above the powder metering device. The fan (E) of the spray-drying unit serves both as conveying means for the product and 25 comminution unit for powder material to be returned. Through a particular design of the spray-drying nozzle, returned powder material from the return line (9) is combined with the corresponding media liquid (5), spray and hot air (4). The powder or granular 30 air (6) material formed is taken up by the fluidized bed and transported further as already described above. passing through the granulation nozzles (C), further medium, which may have a different composition to the medium introduced into the spray nozzle with powder 3.5 return, is sprayed onto the particles formed. Further granulation and re-setting of the particle size distribution take place. Air introduced from. the chambers (1) via the Conidur bases will dry the product 40 to the desired final moisture content. A dynamic filter (G) integrated into the plant will prevent discharge of powder particles into the environment.

Instead of the three granulation nozzles (C), as shown 5 in figure 1, one or more spray nozzles or spray-drying nozzles or alternatively only one, two or more than three granulation nozzles may be installed at corresponding point of the plant. These additional nozzles can be located directly at the beginning of the 10 fluidized bed or moved further to the back. The choice of the location at which the powder material originally formed is re-sprayed once or more than once is also dependent, inter alia, on the residual moisture content that the desired product is intended to have. It goes 15 without saying that a product having a particularly low residual moisture content requires a longer residence time in the fluidized bed after the final spraying than one with a relatively high residual moisture content.

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If desired, different compositions can be applied through the various nozzles to the particle surfaces already formed, enabling particles having a layered structure to be obtained. However, it can also serve to achieve a more uniform particle size distribution.

Furthermore, the plant according to the invention can be operated not only with air as carrier medium, but it is also possible to operate the entire plant in circulation with an inert gas, such as, for example, nitrogen, or with carbon dioxide gas.

The plant is designed in such a way that the parameters amount of liquid, spray pressure, amount of powder returned, amount of hot gas, hot-gas temperature, amount of warm air and warm-air temperature can be regulated individually. The properties of the end product can be adjusted as desired with respect to the moisture content, the particle size and the particle size distribution through the amount of powder returned, the amount of liquid fed in and the spray pressure. Pulverulent products having particle sizes of from 50 to 1000 μ m can be produced as desired in the

plant described. Depending on the mode of operation, 5 the particles can consist of a single chemical substance or exhibit a layered structure of different substances or, depending on the process parameters crystalline have more or less selected, а predominantly amorphous structure, where, in the latter 10 case, the particles can consist either of one component or a mixture of different components.

The formation of the particles is controlled, in particular, by a spray nozzle suitable for the production of spray-dried granular materials which is integrated into the plant. A corresponding embodiment of a spray nozzle of this type is shown in fig. 2.

This spray nozzle is a spray system which consists of a two-component spray nozzle [(1), (2), (3)] which can be heated with hot water and is in turn fitted with a coaxially arranged powder return (4) and a hot-gas surrounding flow (5).

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The advantage of this spray system is that the powder comes into contact directly at the outlet with the liquid droplets produced via the atomization air and is granulated or agglomerated. In order that the granules do not stick together and the surface moisture can be removed, the spray and powder parts are enclosed in a stream of hot gas, where the requisite energy for evaporating the liquid is converted directly. Subsequent drying takes place in the fluidized bed.

In particular also through incorporation of this spraydrying system, it is possible to achieve specific particle sizes.

40 A particular advantage of this spray-drying plant therefore consists in that very different products can be produced in a single plant depending on the process parameters set and on the liquid media to be sprayed.

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For better understanding and for illustration, a general flow chart (fig. 1) of the spray-drying plant described and examples which come within the scope of protection of the present invention, but are not suitable for restricting the invention to these examples, are given below.

Fig. 1 shows a generalized flow chart of a possible embodiment of a spray-drying plant of this type, in which the numerals and/or letters given have the following meanings:

- 1 Air introduction chambers
- 2 Air outlet chambers
- 20 3 Fill port
 - 4 Hot-air feed
 - 5 Liquid feed
 - 6 Spray air
 - 7 Heating medium
- 25 8 Product
 - 9 Powder
 - A Fluidized-bed apparatus
 - B Spray-drying unit
 - C Granulation nozzles
- 30 D Powder metering device
 - E Fan for powder return
 - F Paddle valve
 - G Dynamic filter
- With reference to the components mentioned in the description and given in the flow chart, it is readily possible for the person skilled in the art to construct a corresponding plant by selecting commercially available individual components. It goes without saying to the person skilled in the art working in the specialist area that both additional electrical and mechanical control units must be incorporated for

5 operating the plant in order to be able to regulate and vary the process parameters, as described.

WO 00/76650 - 9 - PCT/EP00/05183

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PATENT CLAIMS

- 1. A process for the production of spray-dried powder material, characterized in that
- a) in a first step, a liquid medium, spray gas, pulverulent material and hot air are combined,
 - b) the pulverulent product formed falls into a fluidized bed, is taken up, fluidized and transported further,
- c) in one or more granulation step(s) is sprayed with further liquid medium, dried and conveyed in the fluidized bed toward the powder metering device, from which
 - d) some of the pulverulent material is returned into the process.
 - 2. The process as claimed in claim 1, characterized in that the liquid medium is a solution, a dispersion or a suspension.

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- 3. The process as claimed in claim 1, characterized in that the returned pulverulent material is comminuted before return.
- 30 4. Process as claimed in claim 1, characterized in that air or an inert gas selected from the group consisting of N_2 , CO_2 or is used both as spray gas and as carrier gas and heating gas.
- 35 5. The process as claimed in claims 1 and 4, characterized in that the gas is circulated.
- 6. The process as claimed in claims 1, 4 and 5, characterized in that the circulated gas is freed from particles by filters and re-fed to the spray nozzles or heated and introduced into the fluidized bed.

- 7. The process as claimed in claims 1 and 4 to 6, characterized in that the gas is freed from particles with the aid of dynamic filters.
- 10 8. The process as claimed in claims 1 and 2, characterized in that the liquid media used have different compositions at different points of the plant.
- 15 9. The process as claimed in claims 1 to 8, characterized in that that particle sizes of from 50 to 1000 μm can be established specifically by varying the parameters spray pressure, amount of liquid, amount of powder returned, hot-air stream and temperature of the hot air.
 - 10. A spray-drying plant, characterized by
 - a) a spray-drying unit (B)
 - b) a fluidized bed (A)
- 25 c) one or more additional spray or atomization nozzles for liquid media (C)
 - e) a powder metering device (D) and
 - f) a powder return (9) with fan (E).
- 11. The spray-drying plant as claimed in claim 10, characterized in that liquid medium (5), spray air (6), pulverulent material (9) and hot air (4) are combined in the spray-drying unit (B).
- 35 12. The spray-drying plant as claimed in claim 10, characterized in that a spray-drying unit (B) is located vertically above a downstream fluidized bed in a spray tower.
- 40 13. The spray-drying plant as claimed in claim 10, characterized in that the spray-drying unit (B) comprises a spray system which consists of a two-component spray nozzle heated by hot water with

- 5 coaxially arranged powder return and hot-gas surrounding flow.
- 14. The spray-drying plant as claimed in claim 10, characterized in that one or more additional spray or atomization nozzles for liquid media (C) can be installed in the fluidized bed at variable locations.
- 15. The spray-drying plant as claimed in claim 10, characterized in that the fluidized bed is followed by a powder metering device (D), which is separated off by a paddle valve (F) and is fed by an overflow (8).
- 20 16. The spray-drying plant as claimed in claim 10, characterized in that some of the product formed is returned, if desired after comminution, into the spray-drying unit (B) via a fly conveyor, in which a fan (E) serves as conveying element.

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- 17. The spray-drying plant as claimed in claim 16, characterized in that the fan (E) simultaneously serves as comminution unit for the returned powder.
 - 18. A spray system consisting of a two-component spray nozzle heated by hot water with coaxially arranged powder return and hot-gas surrounding flow.





(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

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Veröffentlicht:

- Mit internationalem Recherchenbericht.

Zur Erklärung der Zweibuchstaben-Codes, und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regularen Ausgabe der PCT-Gazette verwiesen.

(54) Title: SPRAY-DRYING INSTALLATION AND A METHOD FOR USING THE SAME

(54) Bezeichnung: SPRÜHTROCKNUNGSANLAGE UND VERFAHREN ZU IHRER VERWENDUNG

(57) Abstract: The invention relates to fluidised bed apparatus with an integrated spray-drying device and to a method for using the same. The invention also relates to a method for producing spray-dried powder material, whose product characteristics can be specifically adapted according to the ulterior use of said material.

(57) Zusammenfassung: Die Erfindung betrifft einen Fließbettapparat mit integrierter Sprühtrocknung sowie ein Verfahren zu dessen Verwendung. Gegenstand der Erfindung ist auch ein Verfahren zur Herstellung von sprühgetrocknetem Pulvermaterial, dessen Produkteigenschaften je nach weiterer Verwendung gezielt variiert werden können.



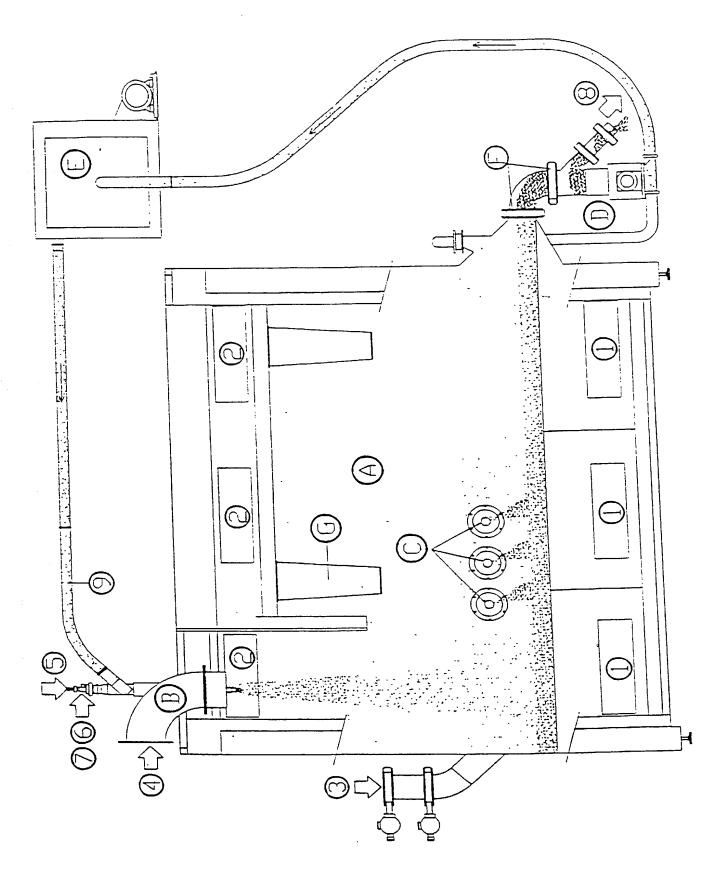
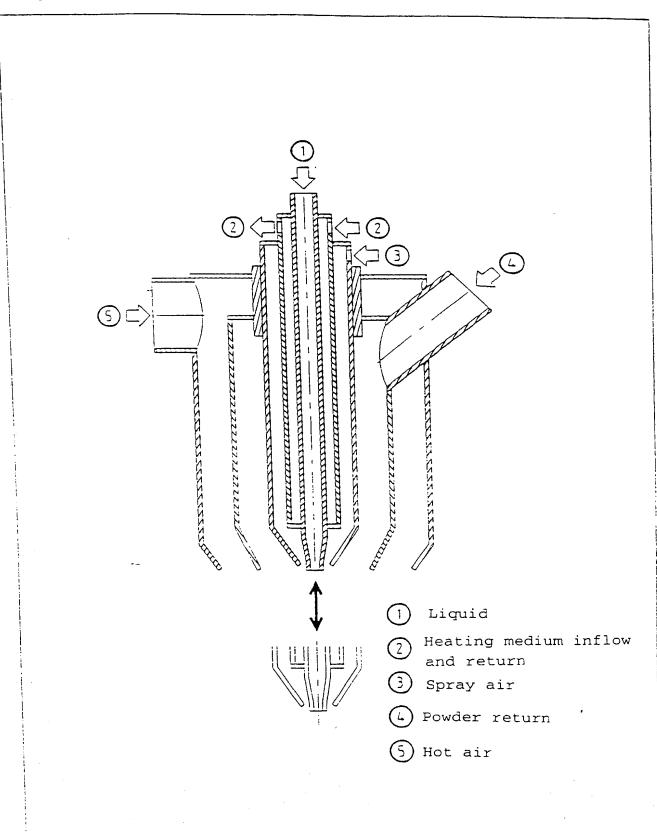


Fig. 1

Fig. 2



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Declaration and Power of Attorney For Patent Application English Language Declaration As a below named inventor, I hereby declare that: My residence, post office address and citizenship are as stated below next to my name, I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled Spray-drying installation and a method for using the same the specification of which (check one) is attached hereto. as United States Application No. or PCT International was filed on 06.06.2000 Application Number PCT/EP00/05183 and was amended on (if applicable) I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56. I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed. **Priority Not Claimed** Prior Foreign Application(s) 16.06.1999 199 27 537.8 Germany (Day/Month/Year Filed) (Country) (Number) (Day/Month/Year Filed) (Country) (Number) (Day/Month/Year Filed) (Country) (Number)

I hereby claim the benefit under application(s) listed below:	er 35 U.S.C. Section 11	9(e) of any United States provisional
(Application Serial No.)		(Filing Date)
(Application Serial No.)		(Filing Date)
(Application Serial No.)		(Filing Date)
Section 365(c) of any PCT Interaction and, insofar as the subject mappior United States of PCT Interaction of 35 U.S.C. Section 112. I ac Trademark Office all information	ernational application datter of each of the claim ernational application in knowledge the duty to con known to me to be not me available betwee	20 of any United States application(s), or esignating the United States, listed below his of this application is not disclosed in the a the manner provided by the first paragraph disclose to the United States Patent and naterial to patentability as defined in Title 37, in the filling date of the prior application and plication:
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (list name and registration number)

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